



MAR - 8 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RECEIVED

Mr. John Chapman, RAC
Manager, Regulatory Affairs
CooperSurgical, Inc.
95 Corporate Drive
TRUMBULL CT 06611

J.R. CHAPMAN

cc: T. Williams
S. Peach (McCue)

Re: P990016
McCue CUBA Clinical Ultrasonic Bone Sonometry System
Received: February 4, 2004

Dear Mr. Chapman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) received your request for a change in ownership from McCue, Plc. (FDA East Reg#9617153) to CooperSurgical, Inc. (FDA Est Reg#1216677). We have changed our records accordingly. All previous regulatory requirements remain in effect and are now the responsibility of CooperSurgical, Inc.

Future correspondence concerning this application should reference the PMA number above and must be submitted to:

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions regarding this letter, please contact Dr. Ewa Czerska at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

cc: Ian McCue, Plc.
Solent Industrial Estate
Shamblehurst Land, Hedge End
Hampshire, United Kingdom SO 30-2FY